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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,553	07/17/2003	Moshe Ein-Gal	1307EIN-US	9245

7590 10/18/2007
Dekel Patent Ltd.
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EXAMINER

LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,553	EIN-GAL, MOSHE	
	Examiner	Art Unit	
	Amanda L. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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This action is in response to the amendment after non-final submission of 5 August 2007. The amendments to the claims are not believed to introduce new matter.

Response to Arguments

Applicant's arguments filed 6 August 2007 have been fully considered but they are not persuasive.

Applicant points out that claim 20 requires a second membrane covering an end face of a reflector. Examiner points out that there is no cited criticality in providing this second membrane, as it is simply described that the end face of the reflector “*may* be covered with another membrane” (emphasis added). As described, this is understood to be an optional feature and is further not disclosed to present any novel or unexpected result over any alternate configurations. Since providing this second reflector solves no stated problem it is considered an obvious matter of design choice within the skill of the art and Examiner maintains that it is well known in the art to include membrane(s) to shield source devices and their associated reflectors from propagation media. Examiner further points out that the following references were cited in the concluding remarks of the Office action of April 10, 2007 as supporting evidence for this statement. Examiner repeats the relevant recitations here:

Oppelt (US 5,279,282) discloses a vibratory membrane in a shockwave source device; Hassler (US 5,309,897) discloses a source device with vibratory membrane and propagation medium (abstract) and an associated reflector [21] having a membrane [12] that coincides with it (col. 4, lines 31-32; also col. 5, lines 7-10); Grunewald (US 5,174,280) discloses a source surrounded by radiating membrane (col. 3, lines 43-64) and a reflector with a surrounding

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membrane that “closes the interior of that liquid-filled space and couples the device acoustically to the body of the patient” (col. 5, lines 1-12).

Since it has been made clear on the record that it is well-known to cover both shockwave source devices and their associated reflectors with membranes for a variety of reasons, as necessitated by the particular therapy method, it is reasonable to conclude that the configuration claimed would have been obvious to one of ordinary skill in the art at the time of invention as a combination of prior art elements to known methods to yield predictable results.

Examiner further maintains that the spatial adjacency of Fig. 3 of Grunewald suggests one device sealingly passes through the membrane of the second. Here, the “sealing rings” are regarded as membrane(s) and it is clear by the figure that the sealing ring of the first device is a membrane through which the second device passes – especially since source(s) labeled P are regarded as one in the same, since they are each represented by the same designation. In this case, source P “sealingly passes” through the sealing ring(s) of E.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 20-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (U.S. Patent No. 5,058,569) in view of Grunewald et al. (U.S. Patent No. 5,224,468).

Regarding claims 20-23 and 25, Hassler '569 discloses a shockwave source device comprising a cylindrical acoustic wave transducer sealed within an excitable membrane and having a longitudinal axis of symmetry (col. 4, lines 10-12; see also coil shockwave source 2 and membrane 1 of Fig. 1) with an at least partially parabolic reflector 33 that is disposed symmetrically on both sides of the longitudinal axis with an end face covered by an external

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membrane (col. 5, lines 19-22; col. 6, lines 55-57 for the “first” external membrane). This first external membrane covering an open end of the device is non-parallel (and generally perpendicular) to the longitudinal axis of symmetry of the device, but it is pointed out that since there is no criticality in providing this feature it is considered an obvious matter of design choice within the skill of the art. Hassler further discloses a propagation medium filling the inner volume of the reflector that separates the reflector from the acoustic wave transducer such that the acoustic waves are reflected towards a focus (col. 5, lines 10-12; lines 30-33). An aperture is formed in the reflector that surrounds the first shockwave source device that is located on the longitudinal axis of symmetry and sealed by a sealing ring (see bore 31 and sealing ring 32; also col. 4, lines 63-68 and col. 5, lines 3-4). The membrane surrounding the source device is excited and moved by the excitation device to generate shockwaves (see voltage generator 20 and col. 5, lines 58-65). A second membrane 1 is disclosed at col. 5, lines 19-22 to surround reflector 33.

Hassler ‘569 does not disclose a second shockwave source device but Grunewald ‘468 discloses a shockwave generating system with two longitudinally axisymmetric shockwave source devices with the second spherical acoustic wave source disposed in an aperture and adapted to emit acoustic waves to a common focus (see first source device P and second source E of Fig. 3; col. 3, lines 35-40). The spatial adjacency of the sources suggests the second device sealingly passes through the membrane (here, the sealing ring is in fact a membrane) of the first device.

The reflectors described in both Grunewald and Hassler are understood to have “reflective surfaces” associated therewith. In Hassler, for one, it is clear that the reflectors have

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different shapes but, alternatively, since there is no stated criticality in providing this feature it is considered to be an obvious matter of design choice within the skill of the art.

Regarding claim 24, the second shockwave source device E of Grunewald '468 is disclosed as a spherical acoustic wave transducer in the embodiment of Fig. 3.

Regarding claim 28, the second shockwave source device E of Grunewald '468 is disclosed as a planar acoustic wave transducer with a focusing lens L that is adapted to focus the shockwaves in the embodiment of Fig. 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Hassler '569 to incorporate a second shockwave source (either planar or spherical) as taught by Grunewald '468 to superposition shockwaves of differing characteristics, such as energy density or focus size, by operating the first and second sources independently for improved disintegration of a calculus (see Grunewald '468 col. 1, line 58 – col. 2, line 2).

3. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (U.S. Patent No. 5,058,569) in view of Grunewald et al. (U.S. Patent No. 5,224,468) and Reichenberger (U.S. Patent No. 4,976,255). The modified invention of Hassler '569 adheres to the invention substantially as claimed except for the first and second shockwave source devices being arranged with respect to one another to focus on different foci.

Reichenberger '255 discloses a first shockwave source device for generating a first focus and a second shockwave source device (therapeutic ultrasound source) converging at a second focus (col. 2, lines 47-60).

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It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to have combined the modified invention of Hassler '569 with the teaching of Reichenberger such that the device was capable of generating two different foci for the purpose of eliminating multiple calculi simultaneously.

4. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (U.S. Patent No. 5,058,569) in view of Grunewald et al. (U.S. Patent No. 5,224,468) and Ein-Gal (U.S. Patent No. 7,048,699). The modified invention of Hassler '569 adheres to the invention substantially as claimed except for the first shockwave source device comprising a conical acoustic wave transducer.

In the same field of endeavor, Ein-Gal '699 discloses a conical acoustic wave transducer enclosed by a membrane for generating shockwaves in a propagation medium (col. 4, lines 53-58).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to have used a conical acoustic wave transducer for the first shockwave source device of the modified invention of Hassler '569, as Ein-Gal teaches the use of a conical transducer for the purpose of directing the focus of the acoustic waves at the apex of the conical transducer (col. 2, lines 33-36).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dory's Ultrasonic pulse apparatus for destroying calculuses (U.S. Patent No. 4,617,931) is relevant regarding use of a spherical acoustic wave transducer in shockwave lithotripsy. Oppelt (US 5,279,282) for a vibratory membrane in a shockwave source device.

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Hassler (US 5,309,897) for a source device with vibratory membrane and propagation medium (Abstract) and an associated reflector [21] having a membrane [12] that coincides with it (col. 4, lines 31-32; also col. 5, lines 7-10). Grunewald (US 5,174,280) for a source surrounded by radiating membrane (col. 3, lines 43-64) and a reflector with a surrounding membrane that “closes the interior of that liquid-filled space and couples the device acoustically to the body of the patient” (col. 5, lines 1-12).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALL

10/15/2007


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